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### (54) Fluid line condition detection

Zustandbestimmung einer Flüssigkeitsschlauchleitung

Détection de l'état d'une conduite en tuyaux pour liquides

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(56) References cited:  
**US-A- 4 530 696**                   **US-A- 4 743 228**  
**US-A- 4 959 050**                   **US-A- 5 087 245**

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**Description****BACKGROUND**

The invention relates generally to monitoring fluid flow, and more particularly, to detecting fluid line conditions upstream of the monitoring position.

Fluid delivery systems having positive pressure pumps for infusing parenteral fluid to a patient have become fairly common. In many cases the pump is a peristaltic type in which a plurality of fingers, rollers, or other devices, sequentially constrict a flexible tube through which the parenteral fluid is supplied. Such fluid delivery systems also include, in addition to the pump, an inverted bottle or bag or other means of supply of parenteral fluid, an intravenous (IV) administration set which is secured to the supply of parenteral fluid and includes the flexible tube, and a cannula which is mounted to the distal end of the tube and which is adapted to be inserted into the patient's blood vessel to thereby infuse the parenteral fluid.

One common problem facing infusion systems is the evaluation of the condition of the fluid supply system upstream of the pump. Where an occlusion of the tube exists upstream of the pump, the pump will not succeed in infusing the parenteral fluid to the patient even though the pump may continue to operate. Where the parenteral fluid supply becomes depleted, once again the pump may continue to operate but no parenteral fluid will be delivered to the patient.

A prior method for detecting depletion of the fluid supply or an upstream occlusion was visual observation. A drip chamber may be inserted in the fluid line at a position downstream from the fluid supply for monitoring the rate and quantity of fluid administered. However, visually verifying the existence of drops requires the time of an attendant which can be an undesirable burden on the hospital staff. Opto-electric drop detectors may be used in conjunction with the drip chamber. These detectors are capable of automatically detecting upstream occlusions due to a clamp or kink in the upstream tubing and an empty IV fluid supply container by detecting an absence of drops. An upstream occlusion can also be detected by the addition of a pressure sensor to the fluid line upstream of the pump. However, the use of these devices can add a considerable additional expense. Additionally, movement of the administration set, if severe enough, can cause extra drops to fall from the drop former or can interrupt the drops causing false counts and false alarms. Ambient light can also interfere with an optical drop sensor and render it inaccurate.

In some cases it would be useful to automatically provide information relating to the pressure of the supply fluid or the "head" pressure. From the head pressure, an upstream occlusion can be detected as well as an empty fluid supply.

Pump systems have been disclosed which include a downstream pressure sensor used for detecting

improper fluid communication with the patient. Such systems include U.S. Patent No. 4,743,228 to Butterfield; U.S. Patent No. 4,460,355 to Layman; U.S. Patent No. 4,534,756 to Nelson; and U.S. Patent No. 4,846,792 to Bobo, Jr. et. al. Where such systems use a pump or other fluid pressure control means which communicates the head pressure to the outlet side of the pump, it would be of value to utilize the existing downstream pressure sensor to determine upstream fluid conditions. This would result in less expense both in the pump and in the administration sets.

Three patents are of particular interest. These are the above-noted Butterfield patent, U.S. Patent No. 4,530,696 to Bisera et. al. and U.S. Patent No. 5,087,245 to Doan. This latter patent is the most pertinent with respect to the present invention. In the Butterfield patent, a fluid flow monitoring method and system are disclosed. These accommodate the situation where wide pressure variations are not expected. In the Bisera patent, a monitor is disclosed for use with an intravenous injection system of the type that includes an accumulator. An alarm is activated where there is no resistance to outflow or occlusion. Finally, in the Doan patent, there is described a system and method for detecting abnormalities in infusion of parenteral fluid by producing perturbation of fluid flow.

Hence, those skilled in the art have recognized the need for a fluid line monitoring system which can automatically detect upstream fluid line occlusions as well as measure the head pressure. Additionally, those skilled in the art have recognized a need to reduce the cost of determining such upstream fluid line conditions. The present invention attempts to fulfill these needs.

**SUMMARY OF THE INVENTION**

Disclosed herein is a fluid line condition detection apparatus as defined in claim 1. Preferred embodiments of that apparatus are defined in dependent claims 2-8.

Also disclosed herein is a method for detecting the condition of a fluid delivery system as defined in claim 9. Preferred embodiments of that method are defined in dependent claims 10-14.

A pressure sensor located in the downstream segment provides a pressure signal representative of the pressure equalization pulse. This pressure equalization pulse is processed to determine upstream fluid conditions. Because this fluid stored in the compliant chamber is at head pressure, the equalization pulse is proportional to the pressure differential between the head and the downstream pressures. The pressure due to the equalization pulse is processed along with the resistance of the downstream system, the compliance of the compliant chamber and the equilibrium pressure to determine the head pressure. From the head pressure, an upstream occlusion and an empty fluid supply can be detected.

In the case of an upstream occlusion, the pump will

produce a large negative pressure; i.e., below atmospheric, very quickly. This results in a large negative equalization pulse at the pressure transducer which is readily identifiable. In the case of detecting an empty supply, the head pressure is compared to a threshold and if the pressure is less than that threshold, an alarm is generated.

Detecting an empty fluid supply may also be accomplished by comparing successively measured head pressures and if the change between them exceeds a threshold, an alarm is generated. A relatively rapid change in head pressure may indicate that the supply fluid is down to the narrow part of the drip chamber.

In another aspect, a float valve or a hydrophilic filter or some similar mechanism which will not pass air may be incorporated into the drip chamber or some other portion of the IV set so that when the fluid supply becomes empty, the line will automatically become occluded. The upstream occlusion detection feature may then be used to also indicate an empty fluid supply.

Other aspects and advantages of the invention will become apparent from the following detailed description and accompanying drawings, illustrating by way of example the features of the invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of an apparatus for detecting conditions in an upstream fluid line incorporating the principles of the invention as applied to an intravascular fluid infusion system;

FIGS. 2A, 2B and 2C are diagrams of the operation of a linear peristaltic pump on a segment of compliant tubing showing in particular the establishment of a compliant fluid chamber; and

FIG. 3 is a block diagram of a signal processing embodiment for determining head pressure in accordance with the invention.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring now to the drawings with more particularity, wherein like reference numerals designate like or corresponding elements among the several views, there is shown in FIG. 1 a system 10 for detecting conditions in a fluid line upstream of a monitoring position. A fluid line, which may be an administration set formed of flexible tubing, is positioned between a fluid supply 12 and a patient 14 and comprises an upstream segment 16, a downstream segment 18 and a pumping segment 44 (shown in FIGS. 2A, 2B and 2C). In this case, the fluid supply comprises an inverted bottle. The pumping segment 44 is operated on by a pressure control means which comprises in this embodiment, an infusion pump 20 to form a compliant chamber as will be described in more detail below. A pressure transducer 22 is coupled to the downstream fluid line segment 18 to sense the

pressure in that segment 18 and provide a signal representative of that sensed pressure. An analog-to-digital converter 24 is coupled to the pressure transducer 22 to provide a digital signal to a signal processor 26 shown in this case as a microprocessor which is part of the pump assembly apparatus.

In FIG. 1, the upstream fluid line segment 16 is connected to the supply bottle 12 through a drip chamber 28 in this embodiment. The upstream segment 16 supplies fluid to the infusion pump 20 which in the embodiment of FIGS. 1 and 2 is a linear peristaltic pump. The pressure of the fluid at the pump inlet 54 will be the "head" pressure. A motor 30 and control electronics 32 are used to drive the peristaltic fingers of the linear peristaltic pump 20. The pump system in this embodiment further comprises the microprocessor 26, a memory 34, an alarm 36, an operator control panel 38 and a display 40. The display unit 40 may comprise a monitor or strip-chart recorder for displaying the head pressure as determined by the microprocessor 26. Mounted at the distal end of the downstream fluid line segment 18 is a cannula 42 used to connect the downstream fluid line segment 18 to the vascular system of the patient 14. The pump 20 supplies the parenteral fluid to the patient 14 at a selected rate and pressure which may be different from the head pressure.

In some prior systems, the output signal from the pressure transducer 22 is processed to detect the existence of a downstream occlusion, infiltration or other condition. Some of these systems are mentioned in the preceding Background section. Thus, a pressure transducer 22 which will supply a pressure signal is already installed in some pump systems.

A typical linear peristaltic pump operates by sequentially pressing on a segment of flexible tubing by means of cam-following fingers. The pressure is applied in sequential locations of the tubing, beginning at the inlet end of the pump and working toward the outlet end. At least one finger is always pressing hard enough to occlude the tubing. As a practical matter, one finger does not retract from occluding the tubing until the next one has already occluded the tubing; thus, at no time is there a direct fluid path from the inlet to the outlet of the pump.

Referring now to FIGS. 2A and 2B, the operation of a linear peristaltic pump 20 in forming a head pressure compliant chamber is shown. The peristaltic pump fingers indicated collectively by numeral 46 create a moving zone of occlusion throughout the length of a pumping segment 44. In FIG. 2A, the most downstream part of the pumping segment or pump outlet 56 is occluded by peristaltic finger 48 while the most upstream peristaltic finger 50 has not yet occluded the pumping segment 44 at the pump inlet 54. Thus, fluid at head pressure is flowing into the pumping segment 44 from the upstream segment 16 but is prevented from communicating with the fluid in the downstream segment 18 by the occlusion caused by the most downstream peristaltic finger 48. Therefore, the pumping

segment 44 is now at head pressure.

In FIG. 2B, formation of the compliant chamber 44 is shown. As discussed above, a second finger occludes before an occluding first finger retracts thereby preventing a direct fluid flow between the supply and the patient. In this case, the upstream finger 50 occludes before the downstream finger 48 retracts and there exists a point in time when both fingers 48 and 50 occlude as is shown in FIG. 2b thereby forming the compliant chamber 44 which traps fluid at head pressure.

In FIG. 2C, the most upstream peristaltic finger 50 continues to occlude the pumping segment 44 prior to the most downstream finger 48 retracting from an occluding position. The fluid at head pressure which was trapped in the compliant chamber 44 is now free to communicate with the fluid in the downstream fluid line segment 18. Thus, the compliant chamber 44 is alternately in fluid communication with the upstream segment 16 and the downstream segment 18 of the fluid line.

When the most downstream peristaltic finger 48 retracts thereby allowing fluid communication with the compliant chamber 44, the most upstream peristaltic finger 50 has already occluded the fluid line, thus a bolus of fluid at head pressure, the bolus being the quantity stored in the compliant chamber 44, is released into the downstream segment 18 of the fluid line. Upon its release, the pressure in the compliant chamber 44 and the pressure in the downstream fluid line segment 18 will equalize. A measurable pressure equation pulse is produced which will be sensed by the pressure transducer 22. This pulse is proportional to the difference between the head and the downstream pressures, and may be processed to determine the head pressure in accordance with the invention.

The flexible material forming the compliant chamber 44 has some compliance ( $C_{pump}$ ) which is taken into account in one embodiment when determining head pressure. It has been found that the compliance is for all practical purposes a property of the tubing because IV fluids are virtually incompressible. When the pressure is changed from  $P_1$  to  $P_2$ , a quantity of fluid "Q" will flow but the quantity is dependent on the tubing compliance as follows:

$$Q = C_{pump} (P_2 - P_1) \quad \text{eq.1}$$

If  $P_2$  is greater than  $P_1$ , flow will occur in a forward direction and if  $P_1$  is greater than  $P_2$ , flow will occur in a backward direction. As used herein, "compliance" refers to a measure of elasticity of the material forming the compliant chamber. It is given here as a constant.

The quantity of fluid Q which will flow is also affected by the resistance R of the fluid system in accordance with the following:

5

where:

R is the total resistance to fluid flow;  
 $P(t)$  is dynamic pressure; and  
 $P_{eq}$  is equilibrium pressure

Substituting  $P_{head}$  for  $P_2$  and  $P_{eq}$  for  $P_1$  in equation 1 and combining equations 1 and 2 yields:

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$$P_{head} = P_{eq} + \frac{1}{RC_{pump}} \int_0^t (P(t) - P_{eq}) dt \quad \text{eq.3}$$

where:

$P_{head}$  is the head pressure; and  
 $C_{pump}$  is the effective compliance of the compliant chamber 44.

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As shown in equation 3 above, equilibrium pressure  $P_{eq}$  and resistance R are also considered when determining the head pressure. Although determination of equilibrium pressure may be based upon a measurement of pressure in the system before perturbation of the fluid flow by the bolus of fluid at head pressure, equilibrium pressure is preferably averaged over a number of pressure readings both before and after the measurement of the pressure response to the bolus. It is not necessary that the equilibrium state be a state of zero flow. The equilibrium pressure is rather a dynamic one, which is monitored and determined periodically. It is only necessary for the fluid system to be in equilibrium prior to release of the head pressure bolus, and the pressure response can be integrated until it again returns to equilibrium. The baseline or equilibrium pressure  $P_{eq}$  is thus average pressure (including that due to flow) in the equilibrium state.

The total fluid flow resistance R is preferably determined by the means disclosed in U.S. Patent No. 5 087 245 (USSN 07/322291), or by the technique disclosed in U.S. Patent 4,743,228 to Butterfield.

The accuracy of this method of determining head pressure depends on the stability of the compliance of the pumping segment 44 from set to set and over time. For use as an occlusion detector, however, great accuracy is not important. If the line is occluded, the pump will produce a large negative pressure; i.e., less than atmospheric very quickly. This results in a large negative equalization-pulse at the pressure transducer 22 which is readily identifiable. However, for use as an empty supply detector, a greater degree of accuracy is needed. The supply would be assumed to be empty if the fluid head pressure fell below a specified minimum

pressure threshold, or if the head pressure began to change rapidly as it would if the level of the supply fluid were down in the narrow part of the drip chamber, or in the tubing itself.

Further associated with the microprocessor 26 and operator control 38 is an alarm generator 36 responsive to comparisons of the head pressure with one or more reference values or thresholds which are stored in the system memory 34. Reference values may also be input into the memory 34 at the operator control 38 or may be preprogrammed.

Referring now to FIG. 3, a processing system 57 for determining head pressure is shown. It is preferable to use as the equilibrium pressure  $P_{eq}$  the average of determinations of pressure before and after the release of the head pressure bolus by the compliant chamber 44. This provides considerable immunity from artifacts such as pressure changes due to patient motion. It should be noted that repeated sampling of downstream pressure is intended to be timed so that samples can be equally spaced in time, at intervals of 0.005 seconds for example.

The equilibrium pressure 58 is determined as described above. A series of dynamic pressure samplings are taken, to be compared with the equilibrium pressure 58 as  $P(t) - P_{eq}$  in the comparator 60. An integrator 62 for calculating the difference over time is adapted to generate a signal representing the integral. This integral signal is received and scaled in the scaler section 64 according to the fluid flow resistance 66 in the infusion system and the compliance 68 of the material forming the compliant chamber 44. Resistance 66 in the infusion system may change over time and the resistance determination may be updated. The compliance 68 is preferably stored in memory at 34 to be accessible to the scaler 64.

Scaling 64 by the fluid flow resistance 66 and the compliance 68 of the compliant chamber 44 results in a value which may be referred to as the differential pressure ( $P_{diff}$ ), to which the equilibrium pressure is added in the adder 70 to determine head pressure. The value of the head pressure is compared in comparator 72 to a first threshold reference value 74 to determine whether the fluid source pressure has fallen below a specified minimum and thereby indicating an empty fluid supply. The head pressure value is compared in comparator 72 to a second threshold reference value 76 to determine if the head pressure is so low as to indicate that an upstream occlusion exists.

The comparator 72 may also be programmed to monitor the change between measurements of head pressure and if the head pressure were to begin to change rapidly, such change may be taken to indicate that the fluid level is down in the neck of the supply bottle or the narrow part of the drip chamber or in the tubing itself in the case where the supply has a greater cross-sectional area than the tubing. Therefore, the difference between successive  $P_{head}$  pressures is compared to a third threshold 78 to determine if such a condition

exists. Monitoring the flow rate 79 to consider its effect on head pressure change can be used in determining the existence of an empty fluid supply container. For example, if the flow rate remained steady while the change in head pressure increased, an empty fluid supply container could be indicated.

In an alternative embodiment, the downstream pressure measurements may be provided to the comparator 72 along line 82 and directly compared in the comparator 72 with a fourth threshold 80 for determining a gross variance with a predetermined minimum, to also detect an upstream occlusion of the fluid line.

Comparator 72 is adapted to generate an alarm signal 82 when the pressure values fall below the threshold values or the change in pressure exceeds a threshold.

The alarm signal 82 is received by an alarm generator 86 for generating an audio and/or visual or other type of alarm signal. Different alarm signals from the comparator 72 may result in different alarms. For example, an occlusion alarm may be a continuous tone while a low head pressure alarm may be a repeating tone. The display 40 displays the head pressure and the alarms as desired and may display other system information. Additionally, the microprocessor 26 may stop pump operation automatically upon issuance of an alarm signal by the alarm generator.

Other implementations of the integrator may include the use of electronic analog integration, hydraulic integration, or mechanical integration. Other methods which can evaluate the integral of a pressure wave can be used to implement this technique. Additionally, other types of pumps may also be used if the pump accommodates a compliant chamber capable of storing fluid at one of the pressures and subsequently connecting the chamber to the portion of the fluid line at the other pressure.

Referring again to FIG. 1, an embodiment is shown in which a float valve 88 is included with the drip chamber so that when the level of fluid in the drip chamber drops below a minimum level, the float valve 88 will occlude the upstream line 16. Continued operation of the pump 20 will produce the large negative pressure in the compliant chamber 44 as mentioned above and the large negative equalization pulse. Thus, the empty supply condition will be signalled through the occlusion alarm. Other similar mechanisms which will not pass air, such as hydrophilic filter, may also be utilized in forcing an occlusion situation when the fluid source becomes empty.

In view of the foregoing, it can be appreciated that the apparatus and method for detecting upstream conditions in the intravenous fluid line in an intravascular fluid administration system provide such detection without the necessity of modifying an existing peristaltic pump mechanism. In the case where a downstream pressure transducer has already been installed, the signal processing can be modified in accordance with the invention to provide such upstream condition detection. The apparatus and method for detecting conditions in

an intravenous fluid line in an intravascular fluid administration system provide a simple, low cost way of monitoring upstream occlusion without the necessity of modification of existing peristaltic pump mechanisms. Placed in a downstream configuration, the system of the invention can be readily adapted to monitor upstream occlusion in existing peristaltic pump IV infusion systems.

Additionally, where the height 90 of the fluid supply above the compliant chamber is known as well as the inner diameter 90 of the upstream tubing and the cross-sectional area 90 of the fluid supply container, the amount of fluid remaining in the fluid supply could be determined from head pressure. Where the flow rate 79 through the pump of the fluid in the tubing is known, the amount of time remaining before the fluid supply is depleted can also be determined.

Although preferred and alternative embodiments of the invention have been described and illustrated, it is clear that the invention is susceptible to numerous modifications and adaptations within the ability of those skilled in the art and without the exercise of inventive faculty. Thus, it should be understood that various changes in form, detail and usage of the present invention may be made without departing from the scope of the invention.

## Claims

1. A fluid line condition detection apparatus (10) coupled between a fluid supply (12) and the vascular system of a patient (14), the apparatus comprising a fluid line having an upstream segment (16) coupled to the fluid supply (12) receiving fluid from the fluid supply (12) at head pressure (54) and a downstream segment (18) coupled to the vascular system of the patient (14); a fluid chamber (44) in the form of a flexible segment (44) coupled in fluid communication with the upstream and downstream segments (16, 18); fluid pressure control means (20) operating on the flexible segment (44) of the fluid line to control the pressure of the fluid in the fluid line and alternately opening the fluid chamber (44) to fluid communication with the upstream segment (16) of the fluid line and with the downstream segment (18) of the fluid line, wherein when opened to the upstream segment (16), the chamber (44) receives and stores fluid at head pressure (54) and wherein when opened to the downstream segment (18), the chamber (44) communicates the fluid stored at head pressure (54) to fluid residing in the downstream segment (18) thereby causing a pressure equalization pulse in the downstream segment (18); pressure sensor means (22) sensing the pressure equalization pulse and providing an equalization signal representative of the pressure equalization pulse and sensing equilibrium pressure in the downstream segment (18) and providing an equilibrium signal representative thereof; resist-

5 ance means (66) providing a resistance signal representative of the resistance to fluid flow downstream of the fluid chamber (44); processor means (57), and an alarm generator (36), the apparatus (10) being characterized by:

10 said flexible segment (44) having a predetermined effective compliance;

15 said processor means (57) taking the difference (60) between the equilibrium signal and the equalization signal, integrating (62) said difference with respect to time and multiplying the integrated difference by the reciprocal of the product of the resistance signal and the compliance, whereby the head pressure (54) is achieved by adding (70) the equilibrium pressure to the above mentioned product, said processor means (57) also providing a head pressure signal representative of the determined head pressure; and

20 25 said alarm generator (36) receiving the head pressure signal, comparing the received signal to a first threshold (74), and if the head pressure signal is less than the first threshold (74), providing an occlusion alarm signal.

2. The apparatus of claim 1, further characterized in 30 that the processor means (57) further comprises adder means (60) adding the integrated difference to said equilibrium signal in determining the head pressure.

35 3. The apparatus of claim 1 or 2 further characterized in that the alarm generator (36) compares the received signal to a second threshold (16) and if the head pressure signal is less than the second threshold (16), provides an alarm signal indicating 40 that the fluid supply (12) is empty.

4. The apparatus of any one of the preceding claims, 45 further characterized in that the processor means (57) also receives the flow rate and compares the change in the flow rate to the change in head pressure to determine the head pressure difference signal.

5. The apparatus of any one of the preceding claims 50 further characterized in that the processor means (57) also receives the size of the fluid line, the size of the fluid supply (12) and the height of the fluid supply (12) and based on head pressure, said sizes and height, determines the quantity of fluid remaining in the fluid supply (12).

6. The apparatus of claim 5, further characterized in 55 that the processor means (57) also receives the flow rate and based on the received flow rate and

the quantity remaining in the fluid supply (12), provides a time remaining signal indicative of the amount of time remaining before the fluid supply (12) is empty.

7. The apparatus of any one of the preceding claims, further characterized in that the fluid pressure control means (20) comprises a peristaltic pump (20) having a plurality of peristaltic means (46) operating on the flexible segment (44) of the tubing sequentially occluding the flexible segment (44).

8. The apparatus of any one of the preceding claims further characterized by valve means (88) preventing the flow of air into the upstream segment (16) of the fluid line when the fluid supply (12) becomes empty, said valve means (88) having a float valve (88).

9. A method for detecting the condition of a fluid delivery system, utilizing the apparatus of any one of claims 1-8, the fluid upstream of the fluid pressure control means (20) being at head pressure, the method being characterized by the steps of:

storing fluid at the head pressure in a fluid chamber (44) disposed in fluid communication with the upstream segment (16) and with the downstream segment (18) of the fluid line;

alternately opening the fluid chamber (44) to fluid communication with the upstream segment (16) of the fluid line and with the downstream segment (18) of the fluid line, wherein when opened to the upstream segment (16), the chamber (44) receives and stores fluid at head pressure and wherein when opened to the downstream segment (18), the chamber (44) communicates the fluid stored at head pressure to fluid residing in the downstream segment (18) thereby causing a pressure equalization pulse in the downstream segment (18);

sensing the pressure equalization pulse and providing an equalization signal representative of the pressure equalization pulse; and processing the equalization signal to determine the head pressure, including the steps of taking the difference between the equilibrium pressure and the equalization signal, integrating the difference with respect to time, and adding the equilibrium pressure in determining the head pressure.

10. The method of claim 9 further characterized in that:  
the step of sensing further comprises the steps of  
sensing equilibrium pressure in the downstream  
segment (18) and providing an equilibrium signal

representative thereof.

11. The method of claim 10 further characterized by:  
the steps of determining the resistance to fluid flow downstream of the fluid chamber (44), providing a resistance signal representative of said resistance and determining the compliance of the material forming the fluid chamber (44); and wherein the step of processing further comprises the step of multiplying the integrated difference by the reciprocal of the product of the resistance signal and the compliance in determining head pressure.

12. The method of claim 9 further characterized in that: the step of processing further involves providing a head pressure signal representative of the determined head pressure; and further involves the step of comparing the head pressure signal to a first threshold (74) and providing an occlusion alarm signal if the head pressure is less than the first threshold (74), the step of processing further involving providing a head pressure signal representative of the determined head pressure; and comparing the head pressure signal to a second threshold (16) and providing an empty supply alarm signal if the head pressure is less than the second threshold (16).

13. The method of claim 9 further characterized in that:  
the processing step further involves the steps of  
comparing determined head pressures to each  
other and providing a head pressure difference sig-  
nal representative of the difference between com-  
pared head pressures; and further involves the step  
of comparing said difference signal to a third  
threshold (78) and providing an alarm signal indi-  
cating that the fluid supply (12) is empty if the differ-  
ence signal exceeds the third threshold (78).

14. The method of claim 9 further characterized by the step of preventing the flow of air into the upstream segment (16) of the fluid line when the fluid supply (12) becomes empty.

45 Patentansprüche

1. Vorrichtung (10) zur Erfassung des Zustands einer Fluidleitung, wobei die Vorrichtung zwischen einem Fluidbehälter (12) und dem Gefäßsystem eines Patienten (14) angeschlossen ist und folgendes umfaßt: eine Fluidleitung mit einem stromaufwärtigen Abschnitt (16), der mit dem Fluidbehälter (12) gekoppelt ist und Fluid von dem Fluidbehälter mit Ruhedruck (54) erhält, und einem stromabwärtigen Abschnitt (18), der mit dem Gefäßsystem des Patienten (14) gekoppelt ist; eine Fluidkammer (44) in Form eines flexiblen Abschnitts (44), der in Fluidverbindung mit dem stromaufwärtigen und stromabwärtigen Abschnitt (16, 18) gekoppelt ist; eine

Fluiddruckregler (20), der auf den flexiblen Abschnitt (44) der Fluidleitung einwirkt, um den Druck des Fluids in der Fluidleitung zu regeln und die Fluidkammer (44) abwechselnd für eine Fluidverbindung mit dem stromaufwärtigen Abschnitt (16) der Fluidleitung und dem stromabwärtigen Abschnitt (18) der Fluidleitung zu öffnen, wobei die Kammer (44) dann, wenn sie für den stromaufwärtigen Abschnitt (16) geöffnet ist, Fluid mit Ruhedruck aufnimmt und speichert, und die Kammer (44) dann, wenn sie für den stromabwärtigen Abschnitt (18) geöffnet ist, das mit Ruhedruck (54) gespeicherte Fluid mit dem in dem stromabwärtigen Abschnitt (18) befindlichen Fluid verbindet, um dadurch in dem stromabwärtigen Abschnitt (18) einen Druckausgleichsimpuls zu erzeugen; einen Druckfühler (22), der den Druckausgleichsimpuls erfaßt und ein Ausgleichssignal absetzt, das dem Druckausgleichsimpuls entspricht, und der den gleichgewichtigen Druck in dem stromabwärtigen Abschnitt (18) erfaßt und ein Gleichgewichtssignal absetzt, welches diesem entspricht; eine Widerstandseinrichtung (66), welche ein Widerstandssignal absetzt, welches dem Widerstand gegen den Fluidstrom unterhalb der Fluidkammer (44) entspricht; einen Prozessor (57) sowie einen Alarmgenerator (36), wobei die Vorrichtung (10) dadurch gekennzeichnet ist, daß:

der flexible Abschnitt (44) eine vorbestimmte wirksame Komplianz besitzt;

der Prozessor (57) die Differenz (60) zwischen dem Gleichgewichtssignal und dem Ausgleichssignal nimmt, die Differenz über die Zeit integriert (62) und die integrierte Differenz mit dem Kehrwert des Produkts aus dem Widerstandssignal und der Komplianz multipliziert, so daß man den Ruhedruck (54) erhält durch Addieren (70) des gleichgewichtigen Drucks zu dem obengenannten Produkt, wobei der Prozessor (57) auch ein Ruhedrucksignal absetzt, welches dem vorbestimmten Ruhedruck entspricht; und

der Alarmgenerator (36) das Ruhedrucksignal empfängt, das empfangene Signal mit einem ersten Schwellwert (74) vergleicht, und dann, wenn das Ruhedrucksignal kleiner ist als der erste Schwellwert (74) ein Okklusionsalarmsignal absetzt.

2. Vorrichtung nach Anspruch 1, des weiteren dadurch gekennzeichnet, daß der Prozessor (57) des weiteren einen Addierer (60) umfaßt, der die integrierte Differenz zu dem Gleichgewichtssignal addiert, wenn der Ruhedruck ermittelt wird.

3. Vorrichtung nach Anspruch 1 oder 2, des weiteren

dadurch gekennzeichnet, daß der Alarmgenerator (36) das empfangene Signal mit einem zweiten Schwellwert (16) vergleicht und dann, wenn das Ruhedrucksignal kleiner ist als der zweite Schwellwert (16), ein Alarmsignal absetzt, welches anzeigt, daß der Fluidbehälter (12) leer ist.

4. Vorrichtung nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß der Prozessor (57) auch die Strömungsgeschwindigkeit erhält und die Änderung der Strömungsgeschwindigkeit mit der Änderung des Ruhedruckes vergleicht, um das Ruhedruckdifferenzsignal zu bestimmen.
5. Vorrichtung nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß der Prozessor (57) auch die Größe der Fluidleitung, die Größe des Fluidbehälters (12) und die Höhe des Fluidbehälters (12) erhält und auf der Basis des Ruhedruckes, der Größen und der Höhe die Menge des in dem Fluidbehälter (12) verbleibenden Fluids bestimmt.
6. Vorrichtung nach Anspruch 5, des weiteren dadurch gekennzeichnet, daß der Prozessor (57) auch die Strömungsgeschwindigkeit erhält und auf der Basis der erhaltenen Strömungsgeschwindigkeit und der in dem Fluidbehälter (12) verbleibenden Menge ein Signal für die verbleibende Zeit absetzt, welches angibt, wieviel Zeit noch verbleibt, bis der Fluidbehälter (12) leer ist.
7. Vorrichtung nach einem der vorhergehenden Ansprüche, des weiteren dadurch gekennzeichnet, daß der Fluiddruckregler (20) eine Schlauchpumpe (20) umfaßt, die eine Vielzahl von Peristaltikeinrichtungen (46) aufweist, die auf den flexiblen Abschnitt (44) der Schlauchleitung einwirken und nacheinander den flexiblen Abschnitt (44) verschließen.
8. Vorrichtung nach einem der vorhergehenden Ansprüche, des weiteren gekennzeichnet durch eine Ventileinrichtung (88), die den Zustrom von Luft in den stromaufwärtigen Abschnitt (16) der Fluidleitung verhindert, wenn der Fluidbehälter (12) leer wird, wobei die Ventileinrichtung (88) ein Schwimmerventil (88) aufweist.
9. Verfahren zur Erfassung des Zustandes eines Fluidleitungssystems unter Verwendung der Vorrichtung nach einem der Ansprüche 1-8, wobei das Fluid oberhalb des Fluiddruckreglers (20) den Ruhedruck besitzt, und das Verfahren gekennzeichnet ist durch die folgenden Schritte:

Speichern des Fluids mit dem Ruhedruck in einer Fluidkammer (44), die mit dem stromaufwärtigen Abschnitt (16) und dem stromabwärtigen

gen Abschnitt (18) der Fluidleitung in Fluidverbindung steht;

abwechselnd die Fluidkammer (44) für eine Fluidverbindung mit dem stromaufwärtigen Abschnitt (16) der Fluidleitung und mit dem stromabwärtigen Abschnitt (18) der Fluidleitung öffnen, wobei die Kammer (44) dann, wenn sie für den stromaufwärtigen Abschnitt (16) geöffnet ist, das Fluid mit Ruhedruck empfängt und speichert, und wobei die Kammer (44) dann, wenn sie für den stromabwärtigen Abschnitt (18) geöffnet ist, das mit Ruhedruck gespeicherte Fluid mit dem in dem stromabwärtigen Abschnitt (18) befindlichen Fluid verbindet, so daß ein Druckausgleichsimpuls in dem stromabwärtigen Abschnitt (18) erzeugt wird;

Erfassen des Druckausgleichsimpulses und Absetzen eines Ausgleichssignals, welches dem Druckausgleichsimpuls entspricht; und Verarbeiten des Ausgleichssignals, um den Ruhedruck zu bestimmen, umfassend die folgenden Schritte: die Differenz zwischen dem gleichgewichtigen Druck und dem Ausgleichssignal nehmen, die Differenz über die Zeit integrieren und den gleichgewichtigen Druck addieren, wenn der Ruhedruck bestimmt wird.

10. Verfahren nach Anspruch 9, des weiteren dadurch gekennzeichnet, daß der Schritt des Erfassens des weiteren die Schritte des Erfassens des gleichgewichtigen Drucks in dem stromabwärtigen Abschnitt (18) und des Absetzens eines dem entsprechenden Gleichgewichtssignals umfaßt.
11. Verfahren nach Anspruch 10, des weiteren gekennzeichnet durch die folgenden Schritte: Ermitteln des Widerstandes gegen den Fluidstrom unterhalb der Fluidkammer (44), Absetzen eines dem Widerstand entsprechenden Widerstandssignals und Ermitteln der Komplianz des Materials der Fluidkammer (44); und wobei der Schritt des Verarbeitens des weiteren den Schritt des Multiplizierens der integrierten Differenz mit dem Kehrwert des Produkts aus dem Widerstandssignal und der Komplianz bei der Ermittlung des Ruhedruckes umfaßt.
12. Verfahren nach Anspruch 9, des weiteren dadurch gekennzeichnet, daß der Schritt des Verarbeitens des weiteren das Absetzen eines dem ermittelten Ruhedruck entsprechenden Ruhedrucksignals umfaßt; und des weiteren den Vergleich des Ruhedrucksignals mit einem ersten Schwellwert (74) und das Absetzen eines Okklusionsalarmsignals, wenn der Ruhedruck kleiner ist als der erste Schwellwert (74), wobei der Schritt des Verarbeitens des weiteren das Absetzen eines dem ermit-

telten Ruhedruck entsprechenden Ruhedrucksignals umfaßt; und den Vergleich des Ruhedrucksignals mit einem zweiten Schwellwert (16) und das Absetzen eines Alarmsignals bei leerem Behälter, wenn der Ruhedruck kleiner ist als der zweite Schwellwert (16).

13. Verfahren nach Anspruch 9, des weiteren dadurch gekennzeichnet, daß der Schritt des Verarbeitens des weiteren den Vergleich der ermittelten Ruhedrücke miteinander und das Absetzen eines der Differenz zwischen verglichenen Ruhedrücken entsprechenden Ruhedruckdifferenzsignals umfaßt; und des weiteren den Vergleich des Differenzsignals mit einem dritten Schwellwert (78) und das Absetzen eines Alarmsignals umfaßt, welches anzeigt, daß der Fluidbehälter (12) leer ist, wenn das Differenzsignal den dritten Schwellwert (78) übersteigt.
14. Verfahren nach Anspruch 9, des weiteren dadurch gekennzeichnet, daß der Zustrom von Luft in den stromaufwärtigen Abschnitt (16) der Fluidleitung verhindert wird, wenn der Fluidbehälter (12) leer wird.

#### Revendications

1. Dispositif de détection de l'état d'une conduite de fluide (10) raccordant une alimentation en fluide (12) au système vasculaire d'un patient (14), dispositif comprenant une conduite de fluide présentant un tronçon amont (16) relié à l'alimentation en fluide (12), recevant du fluide provenant de l'alimentation en fluide (12) à la pression d'énergie potentielle (54) et un tronçon aval (18) relié au système vasculaire du patient (14); une chambre de fluide (44) se présentant sous la forme d'un tronçon flexible (44) relié, en communication de fluide, aux tronçons amont et aval (16, 18); des moyens de régulation de la pression du fluide (20) agissant sur le tronçon flexible (44) de la conduite de fluide pour réguler la pression du fluide dans la conduite de fluide et mettant alternativement la chambre de fluide (44) en communication de fluide avec le tronçon amont (16) de la conduite de fluide et avec le tronçon aval (18) de la conduite de fluide, dans lesquels, lorsqu'elle est ouverte au tronçon amont (16), la chambre (44) reçoit et emmagasine du fluide à la pression d'énergie potentielle (54), et dans lequel, lorsqu'elle est ouverte au tronçon aval (18), la chambre (44) met en communication le fluide emmagasiné à la pression d'énergie potentielle (54) avec le fluide se trouvant dans le tronçon aval (18), générant ainsi une impulsion d'égalisation de pression dans le tronçon aval (18); des moyens de détection de pression (22) détectant l'impulsion d'égalisation de pression et fournissant un signal d'égalisation représentatif de l'impulsion

d'égalisation de pression et détectant la pression d'équilibre dans le tronçon aval (18) et fournissant un signal d'équilibre représentatif de celle-ci ; des moyens de résistance (66), fournissant un signal de résistance représentatif de la résistance à l'écoulement du fluide en aval de la chambre de fluide (44) ; des moyens formant microprocesseur (57) et un générateur d'alarme (36), le dispositif (10) étant caractérisé en ce que :

10 l'édit tronçon flexible (44) a une conformité effective pré-déterminée ;

lesdits moyens formant microprocesseur (57) utilisent la différence (60) entre le signal d'équilibre et le signal d'égalisation, intègrent (62) ladite différence en fonction du temps et multiplient la différence intégrée par l'inverse du produit du signal de résistance et de la conformité, grâce à quoi la pression d'énergie potentielle (54) est obtenue en ajoutant (70) la pression d'équilibre au produit mentionné ci-dessus, lesdits moyens formant microprocesseur (57) fournissant également un signal de pression d'énergie potentielle représentatif de la pression d'énergie potentielle déterminée ; et

15 l'édit générateur d'alarme (36) reçoit le signal de pression d'énergie potentielle, compare le signal reçu à un premier seuil (74) et si le signal de pression d'énergie potentielle est inférieur au premier seuil (74) fournit un signal d'avertissement d'occlusion.

20 2. Dispositif selon la revendication 1, caractérisé en outre en ce que les moyens formant microprocesseur (57) comprennent en outre des moyens d'addition (60) additionnant la différence intégrée audit signal d'équilibre lors de la détermination de la pression d'énergie potentielle.

25 3. Dispositif selon la revendication 1 ou 2, caractérisé en outre en ce que le générateur d'alarme (36) compare le signal reçu à un deuxième seuil (16) et, si le signal de la pression d'énergie potentielle est inférieur su deuxième seuil (16), fournit un signal d'alarme indiquant que l'alimentation en fluide (12) est épuisée.

40 4. Dispositif selon l'une quelconque des revendications qui précèdent, caractérisé en outre en ce que les moyens formant microprocesseur (57) reçoivent également l'indication du débit et comparent le changement du débit à la modification de la pression d'énergie potentielle pour déterminer le signal de différence de pression d'énergie potentielle.

45 5. Dispositif selon l'une quelconque des revendications qui précèdent, caractérisé en outre en ce que les moyens formant microprocesseur (57) reçoivent

également l'indication de la dimension de la conduite de fluide, de la dimension de l'alimentation en fluide (12) et de la hauteur de l'alimentation en fluide (12) et, sur la base de la pression d'énergie potentielle, desdites dimensions et hauteur, détermine la quantité de fluide restant dans l'alimentation en fluide (12).

5 6. Dispositif selon la revendication 5, caractérisé en outre en ce que les moyens formant microprocesseur (57) reçoivent également l'indication du débit et, sur la base de l'indication de débit reçue et de la quantité restante dans l'alimentation en fluide(12), fournit un signal de temps restant indiquant le laps de temps restant avant que l'alimentation en fluide (12) ne soit vide.

10 7. Dispositif selon l'une quelconque des revendications qui précèdent, caractérisé en outre en ce que les moyens de régulation de la pression du fluide (20) comprennent une pompe péristaltique (20) comportant une pluralité de moyens péristaltiques (46) agissant sur le tronçon flexible (44) du tuyau, fermant de manière séquentielle le tronçon flexible (44).

15 8. Dispositif selon l'une quelconque des revendications qui précèdent, caractérisé en outre en ce qu'il comprend des moyens formant clapet (88), empêchant l'écoulement d'air dans le tronçon amont (16) de la conduite de fluide lorsque l'alimentation en fluide (12) est épuisée, lesdits moyens formant clapet (88) étant un clapet à flotteur (88)

20 9. Procédé destiné à détecter l'état d'un système d'alimentation en fluide, utilisant le dispositif selon l'une quelconque des revendications 1-8, le fluide en amont des moyens de régulation de la pression du fluide (20) se trouvant à la pression d'énergie potentielle, procédé caractérisé par les étapes consistant à :

25 emmagasiner du fluide à la pression d'énergie potentielle dans une chambre de fluide (44) placée en communication de fluide avec le tronçon amont (16) et avec le tronçon aval (18) de la conduite de fluide ;

30 ouvrir alternativement la chambre de fluide (44) en communication de fluide avec le tronçon amont (16) de la conduite de fluide et avec le tronçon aval (18) de la conduite de fluide, opération dans laquelle, lorsqu'elle est ouverte au tronçon amont (16), la chambre (44) reçoit et

35 emmagasine du fluide à la pression d'énergie potentielle, et lorsqu'elle est ouverte au tronçon aval (18), la chambre (44) met en communication le fluide emmagasiné à la pression d'énergie potentielle avec le fluide se trouvant dis le tronçon aval (18), générant ainsi une impulsion

- d'égalisation de pression dans le tronçon aval (18) ;  
5 détecter l'impulsion d'égalisation de pression et fournir un signal d'égalisation représentatif de l'impulsion d'égalisation de pression; et traiter le signal d'égalisation pour déterminer la pression d'énergie potentielle, comprenant les étapes consistant à utiliser la différence entre la pression d'équilibre et le signal d'égalisation, intégrer la différence en fonction du temps et ajouter la pression d'équilibre en déterminant la pression d'énergie potentielle.
10. Procédé selon la revendication 9, caractérisé en outre en ce que : l'étape de détection comprend en outre les étapes consistant à détecter la pression d'équilibre dans le tronçon aval (18) et à fournir un signal d'équilibre représentatif de celle-ci.
15. Procédé selon la revendication 10, caractérisé en outre par : les étapes consistant à déterminer la résistance à l'écoulement du fluide en aval de la chambre de fluide (44), à fournir un signal de résistance représentatif de ladite résistance et à déterminer la conformité de la matière formant la chambre de fluide (44); et dans lequel l'étape de traitement comprend en outre l'étape consistant à multiplier la différence intégrée par l'inverse du produit du signal de résistance et de la conformité, lors de la détermination de la pression d'énergie potentielle.
20. Procédé selon la revendication 9, caractérisé en outre en ce que : l'étape de traitement comprend en outre l'étape consistant à fournir un signal de pression d'énergie potentielle représentatif de la pression d'énergie potentielle déterminée ; et comprend en outre l'étape consistant à comparer le signal de pression d'énergie potentielle à un premier seuil (74) et à fournir un signal d'avertissement d'occlusion si la pression d'énergie potentielle est inférieure au premier seuil (74), l'étape de traitement comprenant en outre l'étape consistant à fournir un signal de pression d'énergie potentielle représentatif de la pression d'énergie potentielle déterminée; et à comparer le signal de pression d'énergie potentielle à un deuxième seuil (16) et à fournir un signal d'alarme d'alimentation épuisée si la pression d'énergie potentielle est inférieure au deuxième seuil (16).
25. Procédé selon la revendication 9, caractérisé en outre en ce que : l'étape de traitement comprend en outre les étapes consistant à comparer les pressions d'énergie potentielle déterminées l'une avec l'autre et à fournir un signal de différence de pression d'énergie potentielle représentatif de la différence entre les pressions d'énergie potentielle comparées; et comprend en outre l'étape consis-
30. tant à comparer ledit signal de différence à un troisième seuil (78) et à fournir un signal d'alarme indiquant que l'alimentation en fluide (12) est épuisée, si le signal de différence est supérieur au troisième seuil (78).
35. Procédé selon le revendication 9, caractérisé en outre par l'étape consistant à empêcher que de l'air ne s'écoule dans le tronçon amont (16) de la conduite de fluide lorsque l'alimentation en fluide (12) est épuisée.
40. 50.
- 55.

FIG. 1

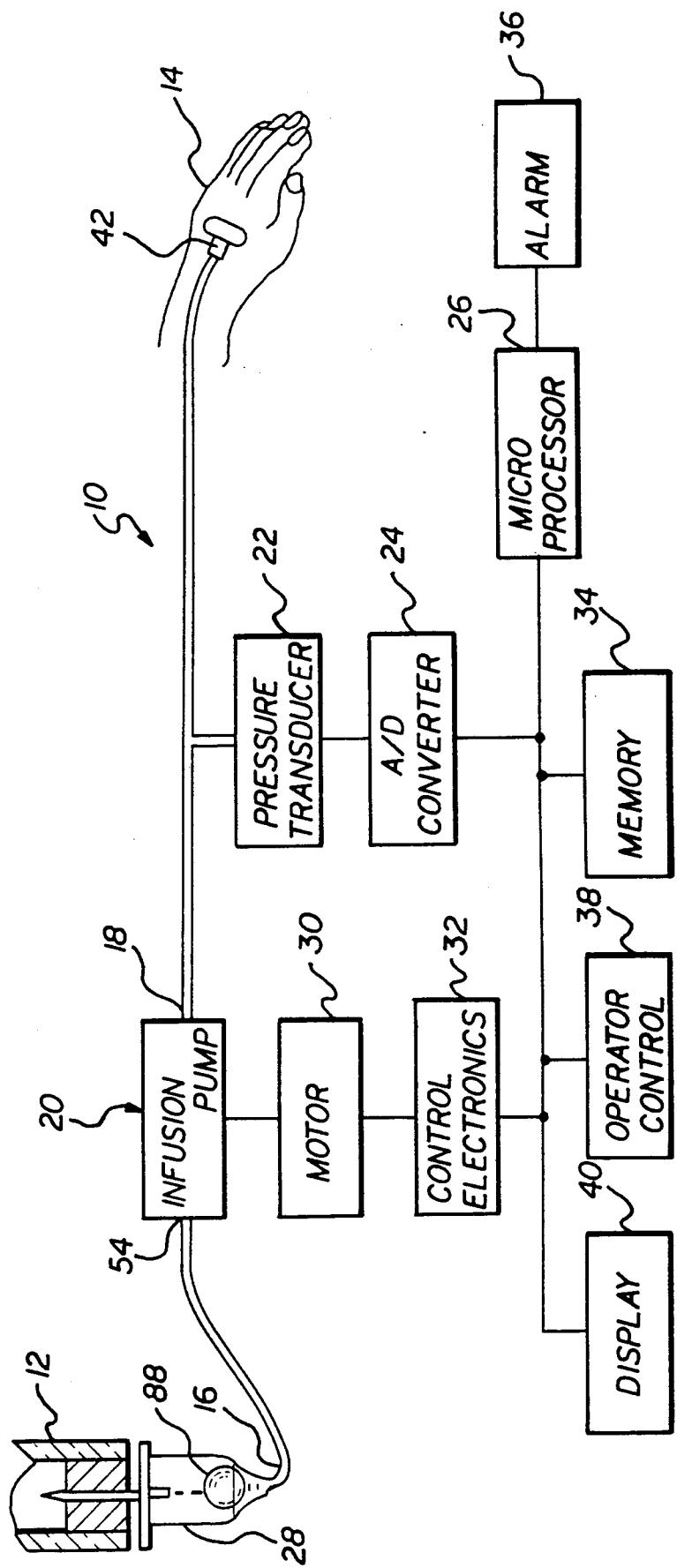


FIG. 2A

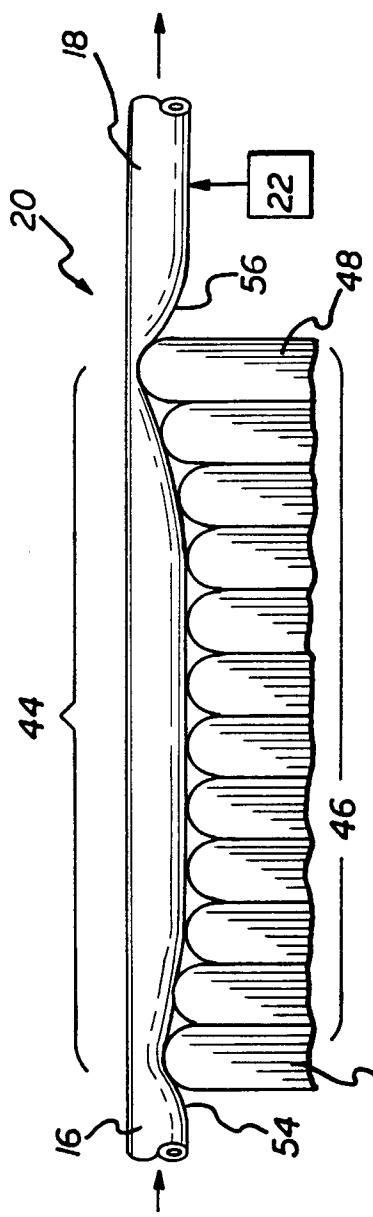


FIG. 2B

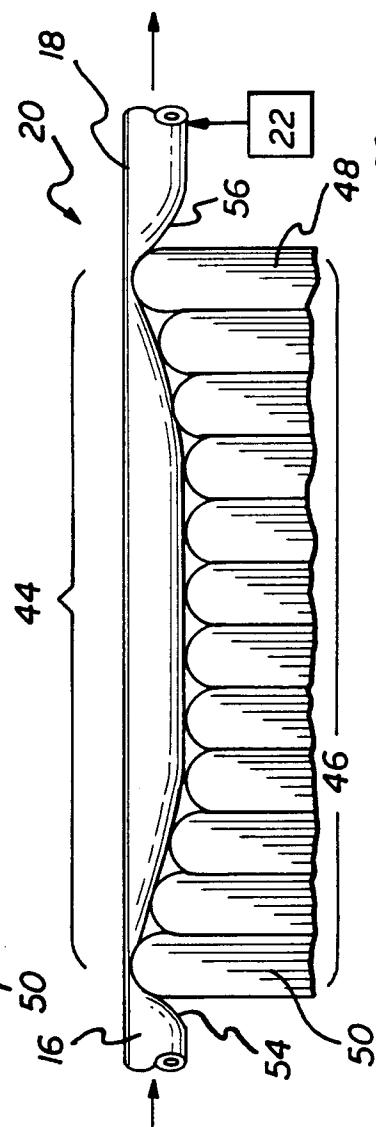
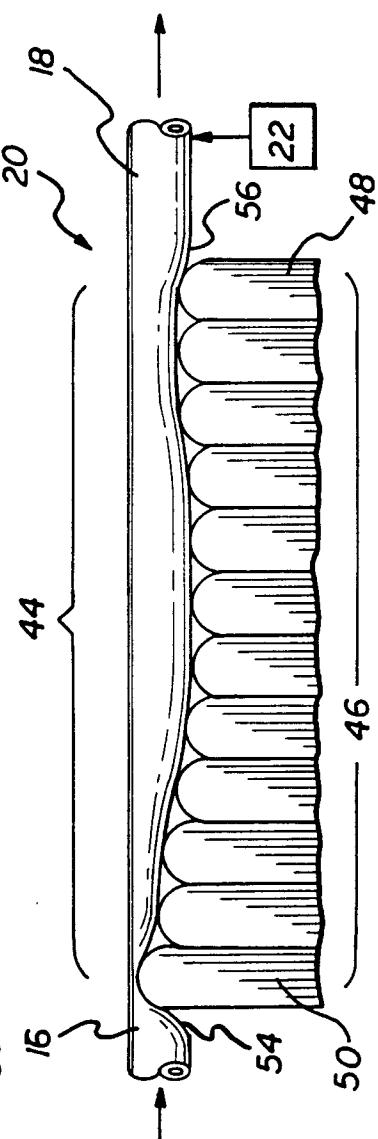


FIG. 2C



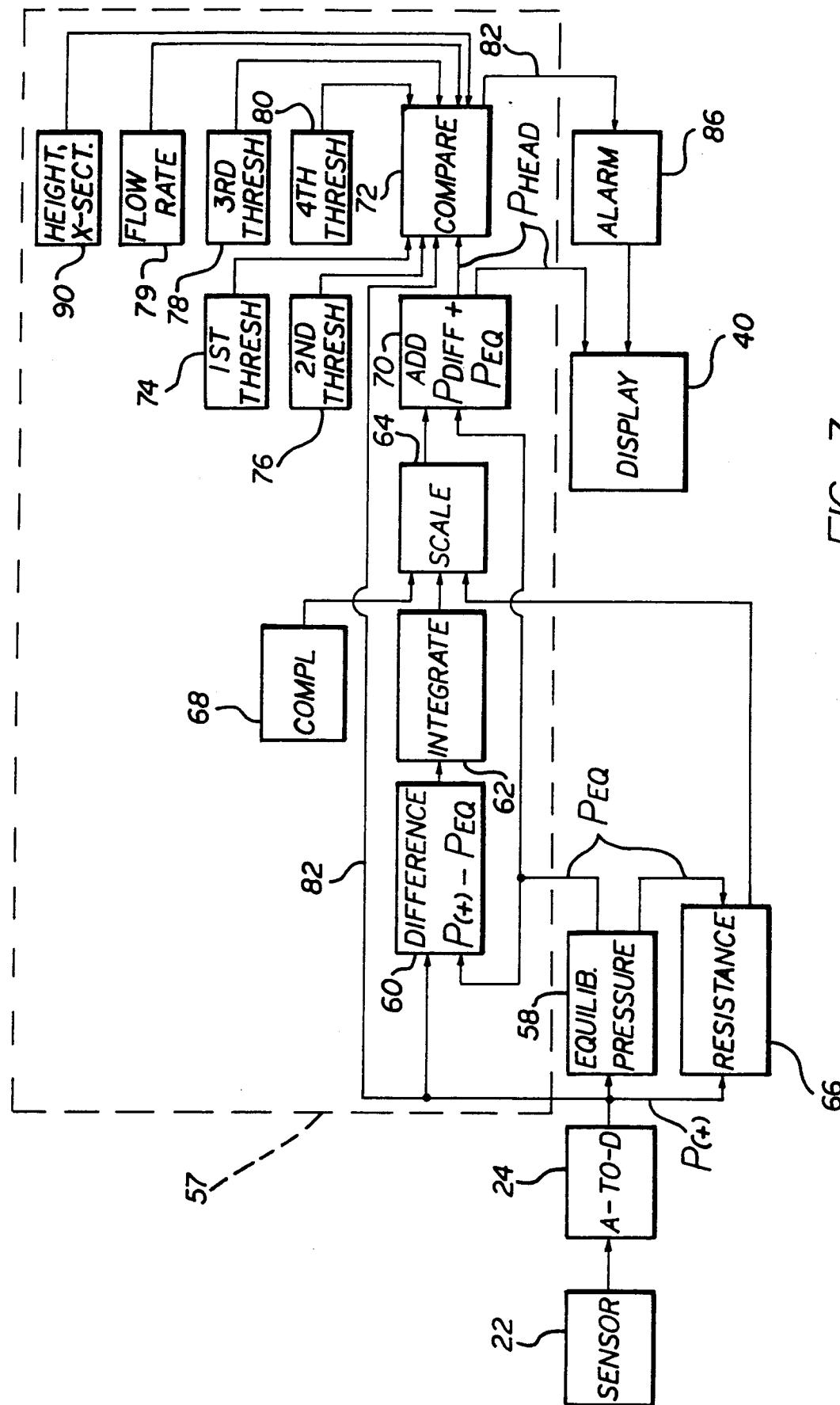


FIG. 3